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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/689,487

10/20/2003

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1291.1134103

7935

28075 7590 09/09/2008
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EXAMINER

WOODALL, NICHOLAS W

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

09/09/2008

PAPER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/689,487
Filing Date: October 20, 2003
Appellant(s): DAVISON, THOMAS W.

J. Scot Wickhem
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/27/2008 appealing from the Office action mailed 12/26/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,792,044	Foley	8-1998
6,206,922	Zdeblick	3-2001
WO 8303189 A	Ash	9-1983

Art Unit: 3733

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 18-23, 25-27, 30-36, 38-41, and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 5,792,044) in view of Ash (WO 8303189 A1) and Zdeblick (U.S. Patent 6,206,922).

Regarding claims 18-23, 25-27, 30-36, 38-41, and 46-48, Foley discloses a system comprising an elongated body that can be useable with at least two fasteners (column 15 lines 3-20) and an elongated viewing element, which can be mounted to the elongated body (column 5 lines 51-65). The elongated body defines an access path between the proximal end and the distal end. Regarding claims 47-48, Foley discloses a device wherein the access path comprises a substantially enclosed passage. Foley fails to disclose a system comprising an elongated body that is expandable at the distal end at a first location and the system further comprising a fixation element with at least two fasteners capable of being passed through the passage of an elongate element. Ash teaches a device for use in minimally an invasive surgical procedure that comprises an elongated body that is expandable at the distal end in order to provide viewing and operation room (page 2 lines 24-35). Zdeblick teaches a system comprising a fixation

Art Unit: 3733

element capable of being passed through the passage of an elongate element in order to fuse to adjacent vertebrae. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Foley wherein the elongate body with an expandable distal end in view of Ash and further comprising a fixation element with at least two fasteners capable of being passed through the passage of an elongate element in view of Zdeblick in order to provide viewing and operation room and to fuse two adjacent vertebrae.

Further regarding claims 18, 27, and 33, the combination of Foley, Ash, and Zdeblick disclose a device wherein the cross-sectional area of the second configuration of the passage at the distal end of the device is capable of providing visualization of two fasteners fixed to two adjacent vertebrae. The examiner believes that the combination having an expandable distal end is capable of allowing a surgeon to view two fasteners fixed to two adjacent fasteners. There is no limitation regarding the viewing of the screws being simultaneously viewed, but the examiner believes that the combination is capable of providing simultaneous viewing of the two fasteners as well. Regarding claims 23 and 36, the combination of Foley, Ash, and Zdeblick disclose a device wherein the at least two fasteners are pedicle screws. The screws of the Zdeblick reference are capable of being inserted into the pedicle and can be interpreted as such. Regarding claims 25, 30, 38, the combination of Foley, Ash, and Zdeblick disclose a device wherein the fixation element is a rod. The fixation element of Zdeblick is a rod-shaped element that can be interpreted as a rod. Regarding claim 34, the combination of Foley, Ash, and Zdeblick disclose a device wherein the shape of the access device

Art Unit: 3733

when expanded is at least partially conical. Regarding claim 39, the combination of Foley, Ash, and Zdeblick disclose a device further comprising a locking member capable of holding the fixation element relative to the threaded fasteners. The Zdeblick reference teaches an embodiment wherein a locking screw (282) is added to prevent the threaded fasteners from backing out (see Figure 10 of the Zdeblick reference).

Regarding claim 40, the combination of Foley, Ash, and Zdeblick disclose a device wherein the threaded fasteners include a convex engagement surface at the proximal end. Regarding claim 41, the combination of Foley, Ash, and Zdeblick disclose a device further comprising a washer capable of engaging the convex engagement surface of the threaded fasteners. The Zdeblick reference teaches an embodiment wherein a washer (375) includes holes (380) that are capable of engaging the convex surface of the threaded fasteners.

(10) Response to Argument

The appellant's argument that the examiner has ignored or misinterpreted the structure of the fixation element or fastener as required by the claims is not persuasive. The claims require a vertebral fixation assembly comprising a plurality of vertebral screws, i.e. at least two threaded fasteners, and a fastener, i.e. a fixation element adapted to engage each of the vertebral screws, wherein the vertebral fixation assembly is capable of being passed through the access device and fixes two adjacent vertebrae. As discussed in the final office action Zdeblick shows a device comprising a vertebral fixation assembly comprising a plurality of vertebra screws (elements 350), i.e. at least two threaded fasteners, and a fastener (for example element 366), i.e. a fixation

Art Unit: 3733

element adapted to engage each of the vertebral screws, wherein the vertebral fixation assembly is passed through an access device and fixes, i.e. fuses, two adjacent vertebrae as required by the claims. Therefore, the examiner believes that Zdeblick clearly shows the limitations as required by the claims and the device of Foley as modified by Ash and further modified by Zdeblick discloses the invention as claimed. The appellant's argument that Foley already teaches an access device providing viewing and operation room and therefore cannot be modified by the Ash reference is not persuasive. Ash discloses a prior art device that provides viewing and operation room (page 1 lines 31-33). Ash further discloses that these access devices are only capable of being used in areas having naturally large cavities or spaces (page 1 lines 33-35 and page 2 lines 1-7). Ash further discloses improving the prior art devices by providing a device capable of being used in surgical procedures that can be used in areas without naturally large cavities (page 2 lines 8-12) to provide viewing and operation room in these areas. Therefore, Ash is teaching to improve upon the prior access device, such as the device of Foley, to provide better viewing and operation room than that provided by the prior art devices. Therefore, the examiner believes that the Foley reference can be modified by the Ash reference because Ash teaches improving the viewing and operating room provided by prior art devices. The appellant's argument that the device of Foley as modified by Zdeblick as further modified by Ash would not provide predictable results is not persuasive. The appellant argues the Ash reference is unable to allow for the passage of implants and/or implant insertion devices and therefore would not produce predictable results. The examiner believes this

Art Unit: 3733

argument is moot. The examiner is not using Ash to teach passing implants and/or implant insertion device through the access device because Foley and Zdeblick clearly disclose these limitations. The Ash reference is being used by the examiner to teach a surgical instrument for performing surgical procedures having a distal end that expands to provide viewing and operation room, wherein the instrument can be used in spinal procedures (page 13 lines 8-24). Therefore, modifying the device of Foley to include an expanding distal end in view of the teachings of Ash would predictably result in an access device having an expandable distal end. Further modification of the Foley device to include the vertebral fixation assembly of Zdeblick as discussed above would predictably result in passing a vertebral fixation assembly through an access device. Therefore, the examiner believes the device of Foley as modified by Ash as further modified by Zdeblick discloses the invention as claimed. The appellant's argument that the device of Foley as modified by Ash as further modified by Zdeblick does not include a cross-sectional area sized to permit visualization of the two fasteners fixed to two adjacent vertebrae is not persuasive. First, the examiner would like to note that the claim does not require the passage to permit visualization of the two fasteners fixed to the vertebrae simultaneously. The device of Foley has a cross-sectional area with a size that permits visualization of the both fasteners fixed to the vertebrae individually. Secondly, Zdeblick discloses a device wherein the access device permits visualization of both fasteners while fixed to the vertebrae simultaneously (see Figure 34 of the reference). Third, the examiner would like to note that the references individually or in combination can provide visualization of the two fasteners while fixed to the vertebrae if

Art Unit: 3733

the vertebral fixation assembly is being used on the cervical area of the spine of a smaller organism. Fourth, this limitation is a functional limitation and the device only needs to have a cross-section area with a size, wherein the size is capable of permitting the visualization of two fasteners fixed to two adjacent vertebrae. Therefore, the examiner believes the device of Foley as modified by Ash as further modified by Zdeblick discloses a device having a cross-sectional area sized to permit visualization of two fasteners fixed to two adjacent vertebrae. The appellant's argument that Foley teaches a device allowing all the steps to be performed through a single working channel cannula and therefore teaches away from the modification is not persuasive. The examiner is not using either the Zdeblick reference or the Ash reference to add any additional cannula. The examiner is using the Zdeblick reference to provide a vertebral fixation assembly passed through an access device and the Ash reference to modify the cannula of Foley to include an expandable distal end. Therefore, Foley disclosing the use of one cannula does not teach away from the modifications because no additional cannulas are being added by the teaching references.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Nicholas Woodall/

Examiner, Art Unit 3733

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/Eduardo C. Robert/

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